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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,596	08/17/2005	Masayuki Ii	084437-0184	1802
22428 7590 03/01/2010 FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007				
EXAMINER KANTAMNINI, SHOUBHA				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/510,596

Applicant(s)

II ET AL.

Examiner

Shobha Kantamneni

Art Unit

1627

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5 and 21-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) NONE is/are allowed.
- 6) ☒ Claim(s) 5 and 21-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/06)
Paper No(s)/Mail Date 10/30/2009, 12/30/2009
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's amendment filed on 11/30/2009, cancelled claims 1-4, 6. Applicant's amendment amended claim 5, and added new claims 21-23.

Note: Applicants elect the species of compound 72 as a non-peptide compound of formula I or II, and an antibacterial agent as a drug in claim 4.

Applicant's amendment overcomes the rejection of claims 1-6 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treatment of severe sepsis comprising administering an effective amount of a particular compound of formula (I) or formula (II), does not reasonably provide enablement for a method for prophylaxis of severe sepsis.

Applicant's amendment overcomes the rejection of claim 6 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant's amendment by deleting the recitation "prodrug" overcomes the rejection of claims 1-6 under 35 U.S.C. 112, second paragraph, as being indefinite.

Applicant's amendment overcomes the rejection of claim 6 under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101.

Applicant's amendment overcomes the rejection of claims 1-3, 5-6 under 35 U.S.C. 102(b) as being anticipated by Ichimori et al. (EP 1063228, PTO-1449).

The rejection of claims 1-6 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14, 31 of copending Application No. 10/433826 is herein withdrawn because the Application No. 10/433826 has been abandoned.

Applicant's cancellation of claims 1-4, overcomes the rejection of claims 1-4 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7-8 of U.S. copending Application No. 12/226446.

Applicant's cancellation of claims 1-4, overcomes the rejection of Claims 1-4 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 7,078,540.

Claims 5, 21-23 are examined herein so far as they read on the elected species.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 5, 21, 23 are rejected under 35 U.S.C. 103(a) as being obvious over Ichimori et al. (EP 1063228).

Ichimori et al. teach a method of treating sepsis or septic shock by administering a compound of formula (Iaa) which is same as instant formula (I). See abstract.

Compound 72 is specified as a preferred compound of formula (Iaa), where R1 is ethyl, R2 is hydrogen, Ar is 2-chloro-4- fluoro phenyl, and n is 2, both l- and d-type. See page 76, Table 1; page 42, paragraph [0137]; pages 86-95, claims. A method of manufacturing an agent for treating septic shock is also disclosed. See page 41, paragraphs [0129]-[0132]; page 85 paragraph [0253]; claims 36, 37.

Ichimori et al. does not explicitly teach a method of treating severe sepsis comprising administering compound 72, i.e does not provide an example.

It would have been obvious to a person of ordinary skill in the art at the time of invention to administer compound 72 in the method of treating sepsis severe because Ichimori et al. teach that the compounds therein which include instant compound 72 are useful in treating sepsis. Accordingly, one of ordinary skill in the art at the time of invention would have been motivated to administer compound 72 with reasonable expectation of success of treating severe sepsis associated with organ failure, hypoperfusion or hypotension.

Response to Arguments

Applicant's arguments have been considered, but not found persuasive as discussed above.

Applicant argues that "Ichimori's disclosure that certain compounds inhibit NO or cytokine production does not teach or enable that the same compounds are effective for the treatment of severe sepsis associated with organ failure, hypoperfusion, and hypotension. For example, Ichimori demonstrated NO and cytokine inhibition in mice

only when compound 1 or 3 was administered one hour before administration of LPS. " These arguments have been considered, but not found persuasive. Ichimori et al. teach a method of treating sepsis or septic shock by administering a compound of formula (Ia) which is same as instant formula (I), and includes instant elected compound 72. See page 95, claims 36-37. One of ordinary skill in the art at the time of invention would have been motivated to administer compound 72 with reasonable expectation of success of treating sepsis associated with organ failure, hypoperfusion or hypotension because Ichimori et al. teach that the compounds therein which include instant compound 72 are useful in treating sepsis.

Applicant argues that "Applicants have found the surprisingly beneficial result that these compounds are able to treat severe and lethal sepsis, which, as noted in the British Medical Bulletin, Vol. 55, pages 212-225 (1999), is an unmet and long-felt need." These arguments have been considered, but not found persuasive as discussed above. Ichimori teaches that the compounds therein of formula (Ia) which are same as instant formula (I), and includes instant elected compound 72 are useful in treating sepsis. Accordingly, one of ordinary skill in the art at the time of invention would be motivated to employ those compounds taught by Ichimori in the method of treating severe sepsis.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 22 is rejected under 35 U.S.C. 103(a) as being obvious over Ichimori et al. (EP 1063228) as applied to Claim 5, 21, 23 above, in view of DeMarsh et al. (US Patent 5,714,469).

Ichimori et al. is applied as discussed above.

Ichimori et al. does not specifically teach an antibacterial drug.

DeMarsh et al. teach that ceftazidime is a known antimicrobial agent routinely used for the treatment of sepsis (col. 2, lines 47-52), where the effective amount being from 1.0 to 100 ng/kg/day (col. 8, lines 18-19, 40-41).

It would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to combine compound 72 as disclosed by Ichimori et al. with ceftazidime as disclosed by DeMarsh et al. for the same purpose of treating sepsis or septic shock. A person of ordinary skill in the art would have been motivated to combine compound 72 as disclosed by Ichimori et al. with ceftazidime as disclosed by DeMarsh et al. because: (1) Ichimori et al. teach compound 72 for treating sepsis or septic shock; and (2) DeMarsh et al. teach that ceftazidime is routinely used for treating sepsis or septic shock. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success in treating sepsis or septic shock with the combination of compound 72 as disclosed by Ichimori et al. and ceftazidime as disclosed by DeMarsh et al.

"It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose The idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Response to Arguments

Applicant's arguments have been considered, but not found persuasive as discussed above.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 5, 21-23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 32 of U.S. Patent No. 6,495,604. Although the conflicting claims are not identical, they are not patentably distinct from each other. One of ordinary skill in the art at the time of invention would

have been motivated to employ compound of formula (I) with reasonable expectation of success of treating sepsis because a method for the treatment of severe sepsis by administering a compound of formula I is claimed in '604.

Response to Arguments

Applicant's arguments have been considered, but not found persuasive as discussed above.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period, will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on Monday-Friday, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shobha Kantamneni
Patent Examiner
Art Unit : 1627

/SREENI PADMANABHAN/
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